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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,759	06/25/1999	KENICHI HIGASHIYAMA	001560-363	2045

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/30/2001

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/331,759

Applicant(s)
Higashiyama et al.

Examiner
Irene Marx

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 15, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-12, 14-22, 28-37, and 39-42 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, 14-22, 28-37, and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 14
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

This Office action replaces the Office action mailed 10/31/01.

The amendment filed October 15, 2001 is acknowledged. Claims 1-3, 6-12, 14-22, 28-37 and 39-42 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-12, 14-22, 28-37 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague indefinite and confusing in the recitation of "pulp form". The specific nature of this "form" cannot readily be assessed. While mention of this term is found at Specification, page 10, paragraphs 1 and 2, there is no clear definition of what is intended. Applicant has failed to define this terminology with any particularity.

Claim 39 is vague indefinite and confusing in the recitation of "pellet form". The specific nature of this "form" cannot readily be assessed. While mention of this term is found at Specification, page 10, paragraphs 1 and 2, there is no clear definition of what is intended. Applicant has failed to define this terminology with any particularity.

Claims 1 and 39 are vague, indefinite and confusing in the recitation of "increasing" and "enhancing" concentrations of ions and of pulp or pellet form. Is the increase and/or enhancement of 0.00001%, 0001%, 1%, 10%, 50%? When a word of degree, such as "increasing" or "enhancing" is used as a limitation, it is necessary to determine whether the specification provides some standard for measuring that degree. See *Seattle Box Company, Inc. V. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). In this case, the specification does not enable one skilled in the art to reasonably establish what may be construed as being within the metes and bounds of the word of degree, "increasing the concentrations of phosphate ions" and "enhancing the production of unsaturated fatty acids". Therefore, one of ordinary skill in the art would not be apprised as to the claimed invention's

scope when the claims are read in light of the specification. See *Ex parte Oetiker*, 23 USPQ2d 1641.

Claims 2 and 3 are vague and indefinite in that it is unclear whether the concentrations of phosphate ions is “increased” to the values indicated or whether this is the baseline amount.

Claims 40 and 41 fail to find proper antecedent basis in claim 1 and 2, respectively, for sodium, magnesium and calcium ions in the culture medium.

Applicant’s arguments have been fully considered but they are not deemed to be persuasive.

Applicant’s statement that claim 1 is drawn to a process for culturing and not a process for producing unsaturated fatty acids is noted. What is the purpose of “culturing” since no product is recovered? Applicants argue “enhancement” of production of an unsaturated fatty acid. But that is not relevant to the invention claimed, since no product is recovered (Response, page 9, paragraph 1).

With regard to the metes and bounds of “subgenus *Mortierella*”, Applicant baldly states that it is clear from the Amano *et al.* reference what is encompassed by the subgenus *Mortierella*. However, there is nothing on the record to substantiate that this reference is authoritative and recognized by those of ordinary skill in the art.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-22 and 38 are/remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sigma Catalogue for the reasons as stated in the last Office action and the further reasons below..

Applicant’s arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that the medium is for insect cells and not for fungi. However, the intended use of the media does not distinguish the media since such undisclosed use is inherent in the media. In order to be limiting, the intended use must create a structural difference between the claimed media and the prior art media. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-12, 14-22, 28-37 and 39-42 are remain rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki *et al. et al.* taken with Manoh *et al.* and Yamaguchi *et al.* (US 5,015,579) for the reasons as stated in the last Office action and the further reasons below.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argument that the optimum medium conditions are dependent on the organism to be cultured are noted. However, they fail to persuade, since in the instant case "organism"

pertains broadly to a genus and subgenus, rather than to a specific strain cultured under specific process parameters. Applicants have not demonstrated on this record that conditions suitable for strains of *Cunningmella elegans* or *Aspergillus*, for example, are not suitable for *Mortierella*.

With respect to adjustment of the proportion of pulp and pellet form, applicant has not presented substantiating and object evidence to demonstrate the significance of “increased” pulp form or pellet form in the culturing of *Mortierella* as claimed in claim 1, for example. As noted previously, these terms are not clearly defined on the present record. If all that is required by the process is the production of biomass, one of ordinary skill in the art would have surely have expected at the time the claimed invention was made that “culturing” strains of *Cunningmella elegans* would produce results substantially similar to those of “culturing” *Mortierella*.

With respect to Applicant’s argument that the references are not directed to members of the subgenus *Mortierella*, it is reiterated that applicant has not established that the study published in the Amano *et al.* reference is definitive to one of ordinary skill in this art regarding taxonomy of *Mortierella*. In any event the disclosure of Suzuki *et al.* regarding the adjustment of ions in the media is deemed relevant to the cultivation of any member of the genus *Mortierella*, regardless of the subgenus.

As noted in the rejection under 35 U.S.C § 112, *supra*, the terminology “proportion of the mycelia in pulp form” and “pellet form” is far from clear. In addition, the results presented in the instant specification pertain to specific members of specific species, and not with any specificity to all members of the genus *Mortierella* or the subgenus *Mortierella*. There is no clear correlation between any results shown in the as-filed disclosure and the invention as claimed.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

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Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.


Irene Marx

Primary Examiner

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